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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,183

09/18/2006

Hiroko Inomata

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

11/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/593,183	Applicant(s) INOMATA ET AL.	
	Examiner Ethan Whisenant	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 JUL 09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,22-26 and 28-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,22-26 and 28-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 SEP 06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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NON-FINAL ACTION

1. The applicant's response (filed 02 JUL 09) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-5, 6-20, 22-26, 28-42** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

5. **Claim(s) 1-2, 7-18, 22-23 and 28-41** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ekenberg [6,218,531(2001)].

Claim 1 is drawn to a method for selectively separating and purifying RNA from a mixture comprising both RNA and DNA.

Ekenberg teach a method of selectively separating and purifying RNA from a mixture comprising both RNA and DNA. As regards the volume and concentration of the DNase solution see Examples 1 and 2 and note especially Column 18, lines 49-53. Furthermore where the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). As regards the limitation which requires that the nucleic acid adsorbing porous membrane has a front area and a back area asymmetrical with each other. Absent a showing to the contrary, the examiner asserts that the nucleic acid adsorbing porous membranes utilized by Ekenberg (e.g. SPECTM silica disks produced by Ansys Corp, Irvine CA – See Column 11, lines 34-54) are inherently asymmetric by virtue of the way they are manufactured. See Column 5, lines 38-55 of Ekenberg. Furthermore, in support of this position the examiner refers the applicant to JP 3,058,342, to which the specification refers; Woodard et al. [US 5,650,506 (1997)] and Thurman et al. [Trends in Analytical Chemistry 19(1) :: 18-26 (2000)]. As regards Claim 7 and 28, see Column 14, lines 1-32. Regarding Claim 12 see Example 2, which begins in Column 17. As regards the wash solution recited in Claim 22, note Column 15, lines 36-47. As regards the recovering solution note Column 19, lines 1-5 wherein Ekenberg teach that the elution buffer(i.e. the recovering solution) is water.

CLAIM REJECTIONS UNDER 35 USC § 103

6. Claim(s) 3-4 and 24-25 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg [US 6,218,531 (2001)] as applied against Claims 1 and 22 above and further in view of Mori et al. [US 2003/0170664 (2003)].

Claim 3 is drawn to an embodiment of the method of Claim 1 wherein the nucleic acid adsorbing porous membrane has a hydrophilic group. **Claim 4** is drawn to an embodiment of the method of Claim 1 wherein the nucleic acid adsorbing porous membrane has a hydroxyl group.

Ekenberg teach, as argued above, a method comprising all of the limitations of Claim 3 (i.e. Claim 1) except Ekenberg do not explicitly teach using nucleic acid adsorbing porous membrane which comprises a hydrophilic group or a hydroxyl group. However, Mori et al. do teach a nucleic acid adsorbing porous membrane which

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comprises hydroxyl group(i.e. a hydrophilic group), see paragraph [0031].. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein the filters of Mori et al. are used in place of the filters taught by Ekenberg. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

7. Claim(s) 5 and 26 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg [US 6,218,531 (2001)] in view of Mori et al. [US 2003/0170664] as applied against Claim 4 and 25 above, and further in view of Iwaki [US 2005/0112656].

Claim 5 is drawn to an embodiment of the method of Claim 1 wherein the nucleic acid adsorbing porous membrane comprises an organic material obtained by saponification of a mixture of acetyl celluloses different from each other in acetyl value.

Ekenberg in view of Mori et al. reasonably suggest a method for selectively separating and purifying RNA from a mixture comprising both RNA and DNA which comprises all of the limitations recited in Claim 5 except these authors do not teach using a nucleic acid adsorbing porous membrane comprising an organic material obtained by saponification of a mixture of acetyl celluloses different from each other in acetyl value. However, as evidenced by at least Iwaki such nucleic acid adsorbing porous membranes were known prior to the instant invention, see ¶ [0126], Therefore,

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absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg in view of Mori et al. wherein the filters of Mori et al. are used in place of the filters taught by Ekenberg. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

CLAIM REJECTIONS UNDER 35 USC § 102/103

8. **Claim(s) 20** is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mori et al. [US 2003/0170664 (2003)]

Claim 20 is drawn to an automated apparatus for the selective separation and purification of RNA from a mixture solution containing DNA and RNA.

Mori et al. teach an automated apparatus comprising all of the structural limitations of Claims 20, see, for example, the claims of Mori et al., Admittedly, Mori et al. do not teach using their apparatus for the selective separation and purification of RNA from a mixture solution containing DNA and RNA. However, this limitation is directed towards the intended use of the apparatus and therefore does not limit the claimed invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As regards the limitation which requires that the nucleic acid adsorbing porous membrane has a front area and a back area asymmetrical with each other. Absent a showing to the contrary, the examiner asserts that the nucleic acid adsorbing porous membranes utilized by Mori et al. are inherently asymmetric by virtue of the way they are manufactured. In support of this position the examiner attention is directed to ¶s [0030] – [0035]. Also the applicant's attention is directed to JP 3,058,342, to which the specification refers.

CLAIM REJECTIONS UNDER 35 USC § 103

9. Claim(s) 19 and 42 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg [US 6,218,531 (2001)] in view of Mori et al. [US 2003/0170664 (2003)] and the Stratagene Catalog [p.39 (1988)].

Claims 19 is drawn to a kit comprising a cartridge for selective separation and purification of nucleic acid wherein the cartridge comprises a container having at least two openings and a nucleic acid-adsorbing porous membrane comprising an organic polymer inside said container, wherein said organic polymer has hydroxyl groups which adsorbs a nucleic acid and wherein the nucleic acid adsorbing porous membrane has a front area and a back area asymmetrical with each other, a nucleic acid-solubilizing reagent comprising at least one of a chaotropic salt, a nucleic acid stabilizing agent, a surfactant, a buffer, a DNase solution, and a defoaming agent, and a pressure difference-generating apparatus. **Claim 42** is drawn to the same kit as recited in Claim 19

Ekenberg teach a method which utilizes all of the reagents recited in Claim 19 and 42. Ekenberg do not teach explicitly teach placing the reagents/apparati described therein into a kit format. However Ekenberg does make clear that kits comprising the reagents and apparati necessary to perform methods in molecular biology were well known at the time of the invention as was the advantages of kits, as evidenced by the Stratagene Catalog which teaches the advantages of kits. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein all of reagents and apparati necessary to perform the method of Ekenberg are assembled into a kit. The ordinary artisan would have been motivated to make this modification of Ekenberg in order to gain the advantages inherent to kits. It is noted that Ekenberg do not teach using a nucleic acid-adsorbing porous membrane comprising an organic polymer which organic polymer has hydroxyl groups which adsorbs a nucleic acid, however, as argued above, Mori et al. do teach a nucleic acid- adsorbing porous membrane comprises an organic polymer organic polymer has hydroxyl groups which adsorbs a nucleic acid. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ekenberg wherein the filters of Mori et al. are used in place of the filters taught by Ekenberg. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09. As regards the limitation which requires that the nucleic acid adsorbing porous membrane has a front area and a back area asymmetrical with each other. Absent a showing to the contrary, the examiner asserts that the nucleic acid adsorbing porous membranes utilized by Ekenberg (e.g. SPECTM silica disks produced by Ansys Corp, Irvine CA – See Column 11, lines 34-54) are

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inherently asymmetric by virtue of the way they are manufactured. See Column 5, lines 38-55 of Ekenberg. Furthermore, in support of this position the examiner refers the applicant to JP 3,058,342, to which the specification refers; Woodard et al. [US 5,650,506 (1997)] and Thurman et al. [Trends in Analytical Chemistry 19(1) :: 18-26 (2000)].

DUPLICATE CLAIMS -WARNING

10. Applicant is advised that should claim 19 be found allowable, Claim 42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

11. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

CONCLUSION

12. **Claim(s) 1-5, 6-20, 22-26, 28-42** is/are rejected and/or objected to for the reason(s) set forth above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -

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5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634

EXAMINER SEARCH NOTES

20 MAR 09 – ECW

and Updated on 04 NOV 09

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Inomata H?/au

Cartridge or column

Silica

Isolation or extraction

DNA or RNA or nucleic

DNase

DeFoam\$ or antifoam

Acetyl celluloses

Saponification

Chaotropic salt or guanidine

Organic or cellulose or nitrocellulose same filter\$